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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,039	03/22/2006	Osamu Ito	Q93989	4432
23373 7590 05/29/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER				
GREGORIO, GUINEVER S				
ART UNIT		PAPER NUMBER		
1793				
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05/29/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/573,039

Applicant(s)

ITO ET AL.

Examiner

GUINEVER S. GREGORIO

Art Unit

1793

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 5 of U.S. Patent No. 6,190,637 B1 (hereinafter '637) in view of Toorongian et al. (Routine Production of 2-Deoxy-2-[18F]fluoro-D-glucose by Direct Nucleophilic Exchange on a Quaternary 4-Aminopyridinium Resin; Nucl. Med. Biol.; Vol. 17, No. 3, pages 273-279; 1990).

'637 teaches a method for manufacturing a [F-18]-fluoride ion used for producing radiofluorinated organic compounds which comprises the steps of bringing [O-18] enriched water containing [F-18]—fluoride ion into contact with a weakly basic anionic exchange which corresponds to ion —containing [18^O] water into a column packed with

an ion exchange resin to collect [18F] fluoride ions (claim 1). Furthermore, '637 teaches a tertiary amine wherein P represents styrene-divinylbenzene copolymer and R1 and R2 represents a butyl group (claim 5). '637, does not teach using a quaternary amine, but Toorongian et al. teaches a quaternary amine resin which allows the combination of the collection step, drying and nucleophilic substitution reactions into a single and very simpler procedure. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a quaternary amine for the anion exchange taught by '637 because it simplifies the procedure and reduces the number of steps which would increase yield and decrease the amount of waste produced.

2. Regarding claim 2, '637 teaches a styrene-divinylbenzene which corresponds to polystyrene-divinylbenzene copolymer as evidenced by the MSDS.

3. Regarding claim 3, although claims 1 or 5 of '637 do not teach the amount of water to use to load the sample onto the column it is reasonable to believe that this is a parameter which one of ordinary skill in the art would be able to ascertain without undue experimentation. Furthermore, it is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. In re Boesch, 205 USPQ 215 (CCPA1980). Additionally, it would have been obvious to one of ordinary skill in the art at the time of the invention have determined the optimum value of a cause effective variable such as [spray droplet size] through routine experimentation in the absence of a showing of criticality in the claimed size. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). It would have been obvious to one of ordinary skill in the art at the time of the invention to have determined

the optimum values of the relevant process parameters through routine experimentation in the absence of a showing of criticality. In re Aller, 105 USPQ 233 (CCPA 1955).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ino et al. (hereinafter '637) (U.S. Pat. No (6,190,637 B1) in view of Toorongian et al. (Routine Production of 2-Deoxy-2-[18F]fluoro-D-glucose by Direct Nucleophilic Exchange on a Quaternary 4-Aminopyridinium Resin; Nucl. Med. Biol.; Vol. 17, No. 3, pages 273-279; 1990). '637 teaches a method for manufacturing a [F-18]-fluoride ion used for producing radiofluorinated organic compounds which comprises the steps of bringing [O-18] enriched water containing [F-18]—fluoride ion into contact with a weakly basic anionic exchange which corresponds to ion —containing [18O] water into a column packed with an ion exchange resin to collect [18F] fluoride ions (claim 1). Furthermore, '637 teaches a tertiary amine wherein P represents styrene-divinylbenzene copolymer and R1 and R2 represents a butyl group (claim 5). '637, does not teach using a quaternary amine, but Toorongian et al. teaches a quaternary amine resin which allows the combination of the collection step, drying and nucleophilic substitution reactions into a single and very simple procedure. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a quaternary amine for the anion exchange taught by '637 because it simplifies the procedure and reduces the number of steps which would increase yield and decrease the amount of waste produced.
5. Regarding claim 2, '637 teaches a styrene-divinylbenzene which corresponds to polystyrene-divinylbenzene copolymer as evidenced by the MSDS.
6. Regarding claim 3, although claims 1 or 5 of '637 do not teach the amount of water to use to load the sample onto the column it is reasonable to believe that this is a parameter which one of ordinary skill in the art would be able to ascertain without undue

experimentation. Furthermore, it is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. In re Boesch, 205 USPQ 215 (CCPA1980). Additionally, it would have been obvious to one of ordinary skill in the art at the time of the invention have determined the optimum value of a cause effective variable such as [spray droplet size] through routine experimentation in the absence of a showing of criticality in the claimed size. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). It would have been obvious to one of ordinary skill in the art at the time of the invention to have determined the optimum values of the relevant process parameters through routine experimentation in the absence of a showing of criticality. In re Aller, 105 USPQ 233 (CCPA 1955).

Response to Arguments

7. Applicant's arguments filed 03/19/2009 have been fully considered but they are not persuasive. '637 teaches a method for 'for manufacturing a [F-18]-fluoride ion which corresponds to a radioactive fluoride compound. The only difference between '637 and applicant's structure is that '637 did not teach a quaternary amine. Examiner cited Toorongian et al. because Toorongian et al. teaches a quaternary amine which allows for the combination of collection steps. Examiner did not cite Toorongian to use the structure taught by Toorongian et al. Examiner cited Toorongian et al. to 1) show that it is known in the art to use quaternary amines for chromatography and 2) the reason one of ordinary skill in the art would modify '637 to use a quaternary amine instead of a tertiary amine.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **GUINEVER S. GREGORIO** whose telephone number is **(571)270-5827**. The examiner can normally be reached on **Monday-Thursday, 10:30-5:00 pm**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curt Mayes can be reached on **571-272-1234**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Art Unit: 1793

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gsg
May 26, 2009

/Melvin Curtis Mayes/
Supervisory Patent Examiner, Art Unit 1793